MAY 1 4 2002

K012658

510(k) SUMMARY

Submitter's name: Surgical Instruments Servicing & Savings, Inc.
723 Curtis Court
Sisters, OR 97759
(541) 549-4164

Date summary prepared: August 10, 2001

Device name:

Proprietary name:	Reprocessed Compression Limb Sleeves
Common or usual name:	Various compression limb sleeves
Classification name:	Compressible limb sleeves, 870.5800.

Legally marketed device for substantial equivalence comparison:

The predicate device for each reprocessed compression limb sleeve is the same sleeve as provided by the original manufacturer.

Description of the device:

The devices that are the subject of this submission are used with a pump system to apply sequential compression to the lower limbs. They are made of a variety of materials and come in various sizes. Some are leg wraps and some are foot wraps. They come from several different original equipment manufacturers as single use devices. Reprocessing includes cleaning, testing, packaging, and sterilization. It allows the compression limb sleeves to be used several times rather than just once.

Intended use of device:

The compression limb sleeves are designed to be used with a pump system to apply sequential compression to the lower limbs to prevent deep vein thrombosis.

Technological characteristics:

The device features of the reprocessed compression limb sleeves and the single use compression limb sleeves are very similar. The materials and dimensions are identical. The technical characteristics, method of use, and compatibility with pump systems are also identical. There are two differences. First, the reprocessed devices are provided sterile while the original devices are not. Second, the reprocessed products can be used several times, while the original products are sold for single use.

Testing conducted:

Each compression limb sleeve is tested for functionality during reprocessing. Validation testing of the sterility protocols have also been completed.

Performance testing:

Comparative performance testing and clinical evaluations were not included as part of this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 4 2002

Surgical Instruments Service
Linda J. Bovard, B.S., RAC
c/o R. S. McQuate & Associates, Inc.
29611Simmons Road
Eugene, OR 97405

Re: K012658
Device Name: Reprocessed Compression Limb Sleeves
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: April 11, 2002
Received: April 12, 2002

Dear Ms. Bovard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K012658

Device name: Reprocessed Compression Limb Sleeves

Indications for Use: The compression limb sleeves are designed to be used with a pump system to apply sequential compression to the lower limbs to prevent deep vein thrombosis.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

Prescription Use X OR Over-The-Counter Use _____

Division of Cardiovascular & Respiratory Devices
510(k) Number K012658